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REPLY UNDER 37 C.F.R. § 1.116
EXPEDITED PROCEDURE
EXAMINING GROUP 1623

PATENT
2059-0106P

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Harold G. BROWN et al.	Conf.:	7324
Appl. No.:	09/880,907	Group:	1623
Filed:	June 15, 2001	Examiner:	KHARE
FOR:	A PHARMACEUTICAL COMPOSITION OF COMPLEX CARBOHYDRATES AND ESSENTIAL OILS AND METHODS OF USING THE SAME		

LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

JAN 28 2004

Sir:

The following information is being provided consistent with Applicants' duty of disclosure. This information was brought to the attention of the undersigned as a result of Interrogatories in another application. The Interrogatories discuss products that are alleged to be material to the other application. These products are ARTHRICARE and FLEXALL.

ARTHRICARE

Neither the inventors nor the undersigned had any information with respect to the ingredients of ARTHRICARE at the time the application was filed. Applicants do not concede that ARTHRICARE is material to the prosecution of the present application since Applicants do not know if this product(s) was on the market prior to filing of the present application.

Applicants do not know the composition of ARTHRICARE that may have existed prior to the time of filing the present application.

The undersigned recently conducted a quick on-line search for the product ARTHRICARE and ordered this product on-line. The undersigned visited at least five local stores and was unable to purchase the product directly. The following information concerning ARTHRICARE is not prior art since the products were purchased in November of 2003, which is two years after the filing date of the present application. The following information is taken from the box for the product(s) and/or is printed on the tube containing the product.

A first product is "ARTHRICARE For Women" "Multi-Action". The active ingredients are capsicum oleoresin (containing capsaicin 0.025%), menthol USP 1.25% and methyl nicotinate 0.25%. The inactive ingredients are listed as follows: aloe vera gel, carbomer, cetearyl alcohol (and) cetearyl glucoside, decyl glucoside, methylparaben, propylene glycol, propylparaben and titanium dioxide. No amounts are listed for the inactive ingredients. The disclosed uses are for temporary relief of minor aches and pains of muscles and joints due to simple backache, arthritis and strains and sprains. The product is a cream and is said to be greaseless. The box has the following information on it: "© Del Pharmaceuticals, Inc. 2001."

A second product is "ARTHRICARE For Women," "Ultra

Strength". The active ingredients are capsicum oleoresin (containing capsaicin 0.075%) and menthol 2%. The inactive ingredients are listed as follows: butylene glycol, carbomer, cetearyl alcohol (and) sodium cetearyl sulfate, cetyl alcohol, diazolidinyl urea, dimethicone, disodium EDTA, di-alpha tocopheryl acetate, glycerin, octyldodecanol, PEG-8 beeswax, phenoxyethanol (and) methylparaben (and) ethylparaben (and) butylparaben (and) propylparaben (and) isobutylparaben, purified water and triethanolamine. No amounts are listed for the inactive ingredients. The disclosed uses are for temporary relief of minor aches and pains of muscles and joints due to simple backache, arthritis and strains and sprains. The product is a cream. The box has the following information on it: "© Del Pharmaceuticals, Inc. 2000."

A third product is "ARTHRICARE For Women," "Silky Dry". The active ingredients are capsicum oleoresin (containing capsaicin 0.025%). The inactive ingredients are listed as follows: colloidal silicone dioxide, fragrance, isopropyl myristate (and) isopropyl palmitate (and) isopropyl stearate, methylparaben, mineral oil, polyethylene, propylparaben, retinyl palmitate with cholecalciferol and dl-alpha tocopheryl acetate. No amounts are listed for the inactive ingredients. The disclosed uses are for temporary relief of minor aches and pains of muscles and joints due to simple backache, arthritis and strains and sprains. The

product is said to go on dry. The box has the following information on it: "© Del Pharmaceuticals, Inc. 2001."

A fourth product is "ARTHRICARE For Women," "Nighttime". The active ingredients are methyl salicylate 30%, menthol USP 1.25% and methyl nicotinate 0.25%. The inactive ingredients are listed as follows: carbomer 940, dioctyl sodium sulfosuccinate, FD&C Blue #1, glycerin, isopropyl alcohol, polysorbate 60, propylene glycol and purified water. No amounts are listed for the inactive ingredients. The disclosed uses are for temporary relief of minor aches and pains of muscles and joints due to simple backache, arthritis and strains and sprains. The product is said to be greaseless. The box has the following information on it: "© Del Pharmaceuticals, Inc. 2000."

A fifth product is "ARTHRICARE For Women," "Extra Moisturizing". The active ingredients are capsicum oleoresin (containing capsaicin 0.025%). The inactive ingredients are listed as follows: allantoin, aloe vera gel, caprylic/capric triglyceride, carbomer, cetyl alcohol, dimethicone, fragrance, methylparaben, mixed fruit complex (citric acid, green tea extract, lactic acid, malic acid), PEG-20 glyceryl laurate, PEG-30 glyceryl laurate, propylparaben, purified water, quaternium-15, sodium citrate, stearyl alcohol and titanium dioxide. No amounts are listed for the inactive ingredients. The disclosed uses are for temporary relief of minor aches and pains of muscles

and joints due to simple backache, arthritis and strains and sprains. The box has the following information on it: "© Del Pharmaceuticals, Inc. 2000."

A copy of the front and back of each of the five products are attached hereto.

FLEXALL

FLEXALL is referenced in the application as filed.

FLEXALL 454 is discussed on page 6 of the application in the "Background and field of the Invention" as follows:

Several of the essential oils (i.e. Menthol, Eucalyptus Oil, Camphor, Peppermint Oil and Wintergreen Oil) are currently used in over-the-counter topical preparations such as BenGay, Mineral Ice, Flexall 454, etc. at concentrations as high as 30%. These topical medication claim pain relief but, according to FDA, act to relieve pain by producing a counterirritation, not by penetrating the skin and acting systemically to reduce inflammation and swelling which are the causes of pain. Also, these medications do not claim to reduce bruising, deep pain, itching, or induce wound healing. It has been noted by Williams and Barry (1989, Internat. J. Pharm., 57, 1989) that some essential oils such as chenopodium, eucalyptus, anise and ylang ylang oils penetrate the skin.

The undersigned did not conduct an on-line search for this product since the relevant information known to Applicant at the

time of filing the application was disclosed in the specification. The inventors have no further information concerning this product.

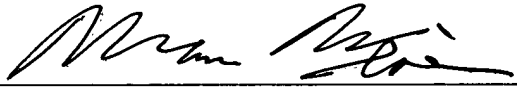
The undersigned purchased "FLEXALL Plus" at a local store in November 2003. The active ingredients are camphor 3.1%, menthol 16% and methyl salicylate 10%. The inactive ingredients are listed as follows: allantoin, aloe barbadensis leaf juice, carbomer, diisopropyl adipate, eucalyptus globules leaf oil, glycerin, mentha piperita (peppermint) oil, SD alcohol 40 (15% w/w), steareth-2, steareth-21, thymus vulgaris (thyme) oil, tocopheryl acetate, triethanolamine and water (234-97). No amounts are listed for the inactive ingredients. The disclosed uses are for temporary relief of minor pain associated with arthritis, simple backache, muscle strains, muscle sprains, bruises and cramps. The product is said to be greaseless. The box has the following information on it: "Dist. By Chattem, Inc... ©2002."

Application No. 09/880,907

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By 

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(703) 205-8000

MSW/sh
2059-0106P



EXTRA MOISTURIZING
ARTHRITIS PAIN RELIEF
FORMULATED FOR WOMEN

ArthriCare® FOR WOMEN

EXTRA MOISTURIZING

ARTHRITIS PAIN RELIEVING CREAM

- EXTRA MOISTURIZING FORMULA
- FAST-ACTING/
LONG-LASTING RELIEF
- ALPHA HYDROXY
AND ALOE TO SOFTEN
AND MOISTURIZE SKIN
- PLEASANT FRAGRANCE

*Women's
Arthritis
Pain Relief*

NET WT 4 fl oz (118 ml)

Also try other
ArthriCare®
Arthritis Pain
Relieving Products:

- ArthriCare® for Women Quick-Drying Formula: Arthritis pain relief in a patented, quick-drying formula.
- ArthriCare® for Women Multi-Action Formula: Triple-action arthritis pain relief plus soothing aloe.
- ArthriCare® for Women Nighttime Formula: 3 pain relievers for warming, fast-acting pain relief to help you sleep.

LOT# 21 EXP# 06



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ArthriCare® FOR WOMEN

EXTRA MOISTURIZING

ARTHRITIS PAIN RELIEVING CREAM

Drug Facts

Active ingredient

Capsicum oleoresin (containing capsaicin 0.025%) . . . Topical analgesic

Purpose

Uses temporarily relieves minor aches and pains of muscles and joints due to:

- simple backache
- arthritis
- strains and sprains

Warnings

For external use only

Do not use

- with a heating pad
- immediately before or after taking a shower or bath

When using this product

- do not get into eyes
- do not bandage tightly
- temporary redness may occur
- avoid contact with mucous membranes, broken or irritated skin

Stop use and ask a doctor if

- symptoms last for more than 7 days
- symptoms clear up and occur again within a few days
- condition gets worse

Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 2 years and older: apply to affected areas not more than 3 to 4 times daily
- children under 2 years: ask a doctor

Other information

- store at room temperature 15°–30° C (59°–86° F)

Inactive ingredients

allantoin, aloe vera gel, caprylic/capric triglyceride, carbomer, cetyl alcohol, dimethicone, fragrance, methylparaben, mixed fruit acid complex (citric acid, green tea extract, lactic acid, malic acid), PEG-20 glyceryl laurate, PEG-30 glyceryl laurate, propylparaben, purified water, quaternium-15, sodium citrate, stearyl alcohol, titanium dioxide

Questions or comments? Call us at 1-800-952-5080

DEL PHARMACEUTICALS, INC.
a subsidiary of Del Laboratories, Inc., Farmingdale, NY 11735
© Del Pharmaceuticals, Inc., 2000

Made in U.S.A.

ArthriCare® has a powerful arthritis pain relief cream with extra moisturizers to meet the needs of women with arthritis and dry skin. ArthriCare for Women Extra-Moisturizing Formula is an advanced 2-in-1 formula that combines a powerful doctor-recommended pain blocker with extra moisturizers, Alpha Hydroxy and Aloe for soft, smooth skin.

347529000

NIGHTTIME ARTHRITIS PAIN RELIEF
FORMULATED FOR WOMEN

ArthriCare[®] FOR WOMEN

NIGHTTIME

ARTHRITIS PAIN RELIEVING CREAM

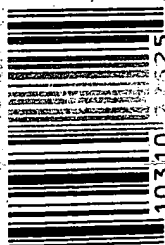
Women's
Arthritis
Pain Relief

NET WT 1.1 oz (31g)

- NIGHTTIME FORMULA RELIEVES PAIN
TO HELP YOU SLEEP
- TRIPLE-MEDICATED FOR WARMING,
FAST-ACTING RELIEF
- GREASELESS, ABSORBS EASILY

LOT C8253

347525000



ArthriCare[®]
FOR WOMEN

ARTHRITIS PAIN RELIEVING CREAM

02/19/04
P/00/01
6

Drug Facts

Active Ingredients

Methyl salicylate 30%
Menthol USP 1.25%
Methyl nicotinate 0.25%

Purpose

Topical analgesic
Topical analgesic
Topical analgesic

Uses

temporarily relieves minor aches and pains of muscles and joints due to:

- simple backache ■ arthritis ■ strains and sprains

Warnings

For external use only

Do not use ■ on wounds or damaged skin ■ with a heating pad, or immediately before or after taking a shower or bath

When using this product

- do not get into eyes ■ avoid contact with mucous membranes, broken or irritated skin
- do not bandage tightly ■ temporary redness may occur

Stop use and ask a doctor if

- condition gets worse ■ symptoms last for more than 7 days or clear up and occur again within a few days

Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.



Drug Facts (continued)

Directions

- read package insert before using
- adults and children 2 years and older: apply to affected areas not more than 3 to 4 times daily
- children under 2 years: ask a doctor

Other information

- store at room temperature 15° - 30° C (59° - 86° F)

Inactive ingredients carbomer 940, dioctyl sodium sulfosuccinate, FD&C Blue #1, glycerin, isopropyl alcohol, polysorbate 60, propylene glycol, purified water

ArthriCare® has a specially formulated powerful arthritis

pain relief cream to meet the needs of women who experience

arthritis pain and are looking for effective nighttime relief.

ArthriCare for Women Nighttime Formula is a greaseless,

triple-medicated formula that absorbs easily, combining 3 pain

relievers for warming, fast-acting pain relief to help you sleep.

ArthriCare®
FOR WOMEN

WOMEN'S
ARTHRITIS PAIN RELIEVING CREAM

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ULTRA STRENGTH ARTHRITIS PAIN RELIEF
FORMULATED FOR WOMEN

ArthriCare[®] FOR WOMEN

ULTRA STRENGTH

ARTHRITIS PAIN RELIEVING CREAM

Women's
Arthritis
Pain Relief

NET WT 1.5 oz (42.5g)

• HIGH POTENCY FORMULA

• TRIPLE-STRENGTH

ARTHRITIS PAIN RELIEF

LOT90451
EXP10/04



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ArthriCare[®]
FOR WOMEN

ULTRA STRENGTH
ARTHRITIS PAIN RELIEVING CREAM

347561002

Drug Facts

Active ingredients

Capsicum oleoresin (containing capsaicin 0.075%)
Menthol 2%

Purpose

Topical analgesic
Topical analgesic

Uses temporarily relieves minor aches and pains of muscles and joints due to:

■ simple backache ■ arthritis ■ strains and sprains

Warnings

For external use only

Do not use ■ with a heating pad, or immediately before or after taking a shower or bath

When using this product

■ do not get into eyes ■ do not apply to wounds or damaged skin ■ do not bandage tightly

Stop use and ask a doctor if ■ condition gets worse ■ symptoms last for more than 7 days

■ symptoms clear up and occur again within a few days

Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

read package insert before using

Adults and children 2 years and older

Children under 2 years

apply to affected areas not more than 3 to 4 times daily

consult a doctor

Drug Facts (continued)

Other information

■ as part of the warming action, temporary redness may occur
■ store at room temperature 15° - 30° C (59° - 86° F)

Inactive ingredients

butylene glycol, carbomer, cetyl alcohol (and) sodium cetearyl sulfate, cetyl alcohol, diazolidinyl urea, dimethicone, disodium EDTA, di-alpha tocopheryl acetate, glycerin, octyldodecanol, PEG-8 beeswax, phenoxethylalcohol (and) methylparaben (and) ethylparaben (and) butylparaben (and) propylparaben (and) isobutylparaben, purified water, triethanolamine

ArthriCare® has a powerful, high potency arthritis pain relief cream to meet the needs of women who experience arthritis pain and want a higher potency pain reliever. ArthriCare for Women Ultra Strength Formula is a triple strength, creamy formula combining a powerful doctor-recommended pain blocker plus a second pain reliever for fast-acting, long-lasting and deep penetrating pain relief.

ArthriCare®
FOR WOMEN

ULTRA STRENGTH
ARTHRITIS PAIN RELIEVING CREAM

DEL PHARMACEUTICALS, INC.,

a subsidiary of Del Laboratories, Inc., Farmingdale NY 11735 ©Del Pharmaceuticals, Inc., 2000 Made in USA

INSTANT DRYING ARTHRITIS PAIN RELIEF
UNIQUELY FORMULATED FOR WOMEN

ArthriCare[®] FOR WOMEN

SILKY DRY

ARTHRITIS PAIN RELIEVING CREAM

Women's
Arthritis
Pain Relief

NET WT 1.5 OZ (42.5g)

LOT40364 EXP10/04

- PATENTED FORMULA GOES ON DRY
- FAST-ABSORBING, FAST-RELIEF
- VITAMINS E AND A TO NOURISH
AND MOISTURIZE SKIN
- PLEASANT POWDER-FRESH SCENT



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347372001

ArthriCare[®]
FOR WOMEN

SILKY DRY
ARTHRITIS PAIN RELIEVING CREAM

Drug Facts

Active ingredient

Capsicum oleoresin (containing capsaicin 0.025%)

Purpose

Topical analgesic

Uses

temporarily relieves minor aches and pains of muscles and joints due to:

- arthritis
- simple backache
- strains and sprains

Warnings

For external use only

Do not use ■ with a heating pad, or immediately before or after taking a shower or bath

When using this product ■ do not get into eyes ■ do not bandage tightly ■ do not apply to wounds or damaged skin

Stop use and ask a doctor if ■ condition gets worse ■ symptoms last for more than 7 days

■ symptoms clear up and occur again within a few days

Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

read package insert before using

Adults and children 2 years and older Apply to affected areas not more than 3 to 4 times daily

Children under 2 years Ask a doctor

Drug Facts (continued)

Other information

■ as part of its warming action, temporary redness may occur ■ store at room temperature 15°-30°C (59°-86°F)

Inactive ingredients

colloidal silicone dioxide, fragrance, isopropyl myristate (and) isopropyl palmitate (and) isopropyl searate, methylparaben, mineral oil, polyethylene, propylparaben, retinyl palmitate with cholecalciferol, di-alpha tocopheryl acetate.

ArthriCare® has a revolutionary, powerful arthritis pain relief cream uniquely formulated to meet the needs of women with arthritis. ArthriCare for Women Silky Dry Formula is a patented formula that goes on dry, combining a powerful doctor-recommended pain blocker with a powder-fresh fragrance and Vitamins E and A to nourish and moisturize the skin.

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U.S. Patent Number 5,178,881

For more information call 1-800-952-5080 or visit www.arthricare.com

ArthriCare®
FOR WOMEN

SILKY DRY
ARTHRITIS PAIN RELIEVING CREAM

TH FORMULA

15
P 151118
5/02

**33%
MORE
FREE**

THAN 1.5 oz SIZE

MULTI-ACTION ARTHRITIS PAIN RELIEF
FORMULATED FOR WOMEN

ArthriCare®
FOR WOMEN

MULTI-ACTION

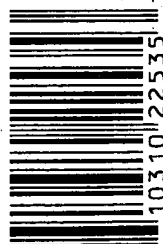
ARTHRITIS PAIN RELIEVING CREAM

Women's
Arthritis
Pain Relief

NET WT 2.0 oz (56.7g)

LOTAC371
EXP11/04

- MULTI-ACTION PAIN RELIEF FORMULA
- FAST-ACTING, LONG-LASTING
DEEP PENETRATING
- WITH SOOTHING ALOE



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347535800

ArthriCare®
FOR WOMEN

MULTI-ACTION
ARTHRITIS PAIN RELIEVING CREAM

Drug Facts

Active Ingredients

Capicum oleoresin (containing capsaicin 0.025%)
Menthol USP 1.25%
Methyl nicotinate 0.25%

Purpose

Topical analgesic
Topical analgesic
Topical analgesic

Uses

temporarily relieves minor aches and pains of muscles and joints due to:
■ simple backache ■ arthritis ■ strains and sprains

Warning

For external use only

Do not use ■ with a heating pad, or immediately before or after taking a shower or bath.

When using this product ■ do not apply to wounds or damaged skin ■ do not get into eyes ■ do not bandage tightly

Stop use and ask a doctor if

■ condition gets worse ■ symptoms last for more than 7 days ■ symptoms clear up and occur again within a few days.

Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)

Directions read package insert before using

adults and children 2 years and older apply to affected areas not more than 3 to 4 times daily

children under 2 years ask a doctor

Other information

■ as part of its warming action, temporary redness may occur

■ store at room temperature 15° - 30° C (59° - 86° F)

Inactive ingredients

aloe vera gel, carbomer, cetearyl alcohol (and) cetearyl glucoside, decyl glucoside, methylparaben, propylene glycol, propylparaben, titanium dioxide

ArthriCare® has a powerful pain relief cream in a multi-action formula to meet the unique needs of women who experience arthritis pain. ArthriCare for Women Multi-Action Formula is a triple action, greaseless formula, combining a powerful doctor-recommended pain blocker plus two added pain relievers for fast-acting, long-lasting and deep penetrating pain relief, plus Aloe to soothe a woman's sensitive skin.

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For more information call 1-800-952-5080 or visit www.arthricare.com

ArthriCare®
FOR WOMEN

MULTI-ACTION
ARTHRITIS PAIN RELIEVING CREAM

Triple Action
Powerful Full Speed Pain Relief
With 3 Proven Pain Relievers

**PENETRATING RELIEF FROM PAINFUL
MUSCLES AND JOINTS DUE TO:**

Arthritis Backache Muscle Strains and Sprains
GREASELESS STAINLESS EASY TO APPLY

0044527-01

Maximum Strength
FLEXALL[®]
Plus

Maximum Strength
Flexall[®]
Plus

Pain Relieving Gel

Pain Relieving Gel with Analgesic Base Net Wt 2.0Z (56.6g)

004452701



Maximum Strength

Flexall[®]
Plus

Maximum Strength Flexall[®] Plus has a Triple Action formula with the maximum level of a pain reliever, the most of any pain rub, plus two additional pain relievers for Triple Action relief that penetrates deep, heats fast and relieves quickly.

Drug Facts

Active Ingredients

Camphor 3.1% Topical analgesic
Menthol 16% Topical analgesic
Methyl salicylate 10% Topical analgesic

Uses temporarily relieves minor pain associated with:

- muscle sprains ■ bruises ■ cramps
- simple backache ■ arthritis ■ muscle strains

Warnings

For external use only

Allergy alert: Do not use if you are allergic to salicylates (including aspirin) unless directed by a doctor.

When using this product ■ use only as directed ■ do not bandage tightly or use a heating pad ■ avoid contact with eyes or mucous membranes ■ do not apply to wounds or damaged skin

Stop use and ask a doctor if ■ condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days ■ redness is present ■ irritation develops

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center right away.

Directions

adults and children over 12 years: ■ apply generously to affected area ■ massage into painful area until thoroughly absorbed into skin ■ repeat as necessary, but no more than 4 times daily
children 12 years or younger: ask a doctor

Inactive ingredients allantoin, aloe barbadensis leaf juice, carbomer, diisopropyl adipate, eucalyptus globulus leaf oil, glycerin, mentha piperita (peppermint) oil, SD alcohol 40 (15% w/w), steareth-2, steareth-21, thymus vulgaris (thyme) oil, tocopheryl acetate, triethanolamine, water (234-97)

Maximum Strength

Flexall[®]
Plus

Pain Relieving Gel



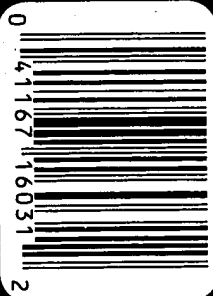
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Flexall[®]
plus

Maximum Strength



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